

Docket No.: TJU00014-100  
Serial No. 09/820,215

PATENT  
Filed: March 27, 2001

### REMARKS

#### Status of the Claims

Claims 1, 3, 4, 6-11, 13-15 and 37-47 are pending in the application.

Claims 1, 3, 4, 6-11, 13-15 and 37-47 have been rejected.

By way of this amendment, claims, 1 and 4 have been amended and claim 3 has been cancelled.

Upon entry of the amendment claims 1, 4, 6-11, 13-15 and 37-47 will be pending.

#### Summary of the Amendment

Claims 1 and 4 have been amended to refer to the elimination of CD34+ cells using "an anti-CD34 antibody based affinity process." Support for the amendment is found throughout the specification, particularly page 15, lines 9 and 10.

#### Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-4, 6-11, 13-15 and 37-47 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office alleges that the claims contain new matter. Applicants respectfully disagree.

It is asserted that applicants' disclosure of 26 epithelial cell markers is not a representative number sufficient to support a genus claim because there are over 20,000 known human genes, an unknown number of which are epithelial cell markers. Applicants respectfully urge that the number is representative since the markers themselves are not being claimed as products *per se*. Those skilled in the art readily recognize the members of the genus as such and it is reasonable that the claimed process is predictable for the entire genus. Those skilled in the relevant art would clearly

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conclude that the inventors, at the time the application was filed, had possession of the claimed invention.

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 112 be withdrawn.

#### Rejection under 35 U.S.C. § 102

Claims 1, 3, 4, 7-11, 13, 37-40 and 42-45 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Ts'o *et al.* (United States Patent Number 5,962,237, hereinafter "Ts'o"). Ts'o discloses removal of white blood cells prior to detection of mRNA that encodes PSA.

Applicants have amended independent claims 1 and 4 to recite that CD34+ cells are removed by "an anti-CD34 antibody based affinity process." Ts'o neither teaches nor suggests such a step. Methodology disclosed by Ts'o as removing all white cells including inherently CD34+ cells is not an anti-CD34 antibody based affinity process. Column 11 line 62 to column 12 line 24 disclose using antibodies to remove various white blood cells based upon a list of markers which does not include CD34. Ts'o does not anticipate the claims.

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 102 be withdrawn.

#### Rejections under 35 U.S.C. § 103

Claims 6 and 41 stand rejected under 35 U.S.C. § 103 as allegedly unpatentable over Ts'o in view of Elliot (United States Patent Number 5,885,574, hereinafter "Elliot"). Ts'o discloses removal of all white blood cells prior to detection of mRNA that encodes PSA, or, alternatively, removal of white cells with specific markers, none of which being CD34. Elliot teaches eliminating CD34+ cells using a CD34 Progenitor Cell Isolation Kit. It is asserted that in view of the teachings in Elliot it would be obvious to modify the teachings of Ts'o. Applicants respectfully disagree.

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Ts'o neither teaches nor suggests specifically eliminating CD34+. One skilled in the art would not be motivated to remove CD34+ cells in view of the teachings of Ts'o which discloses removal of all white blood cells or select subpopulations of white blood cells. One skilled in the art would not be motivated to specifically remove CD34+ cells, i.e. the subpopulation which Applicants have found to be a source of false positives in PCR protocols. Nothing in Ts'o teaches or suggests the specific elimination of CD34+ cells. Ts'o teaches removal of other subpopulations, not CD34+ cells. Ts'o teaches away from the elimination of CD34+ cells by antibody based affinity methods. Moreover, even when combined with Elliot, nothing in the combination teaches or suggests the unexpected elimination of false positives.

Claims 6 and 41 are not obvious over Ts'o in view of Elliot.

Claims 14-15 and 436-47 stand rejected under 35 U.S.C. § 103 as allegedly unpatentable over Ts'o in view of Waldman *et al.* (cancer Epidemiology, Biomarkers and Prevention 1998, hereinafter "Waldman"). Ts'o, discloses removal of all white blood cells prior to detection of mRNA that encodes PSA, or, alternatively, removal of white cells with specific markers, none of which being CD34. Elliot teaches GCC as a epithelial cell cancer marker. It is asserted that in view of the teachings in Waldman it would be obvious to modify the teachings of Ts'o. Applicants respectfully disagree.

Applicants have amended independent claims 1 and 4 to recite that CD34+ cells are removed by "an anti-CD34 antibody based affinity process." Nothing in Ts'o teaches or suggests the specific elimination of CD34+ cells. Ts'o teaches removal of other subpopulations, not CD34+ cells. Ts'o teaches away from the elimination of CD34+ cells by antibody based affinity methods. Nothing in Waldman makes up for this deficiency in Ts'o. Even when Ts'o and Waldman combined with Waldman, The combination of Ts'o and Waldman do not produce the claimed invention, much less . teach or suggest the unexpected elimination of false positives.

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 103 be withdrawn.

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**Conclusion**

The examination of these claims and passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at 215.665.5592 to clarify any unresolved issues raised by this response.

As indicated on the transmittal accompanying this response, the Commissioner is hereby authorized to charge any debit or credit any overpayment to Deposit Account No. 50-1275.

Respectfully submitted,



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